SUMMARY OF THE
ELAB PBMS WORKGROUP TELECONFERENCE
JULY 31, 1998

The Performance Based Measurement Systems (PBMS) workgroup of the Environmental Laboratory Advisory Board (ELAB) convened by teleconference on July 31, 1998, at 1 p.m. The meeting was led by its chair, Mr. Jerry Parr. This committee was formed by ELAB during its meeting of meeting of July 1, 1998. Action items are given in Attachment A. The list of participants is given in Attachment B. A draft list of key elements of a PBMS, provided to the committee prior to the meeting, is given in Attachment C. *The purpose of this meeting was to discuss, revise, and expand the draft list of key elements of a PBMS.*

INTRODUCTION

Mr. Parr opened the meeting by noting that various U.S. Environmental Protection Agency (EPA) offices have drafted PBMS implementation plans which this committee should review. He continued by asking for revisions to the minutes of the previous meeting of the committee. As there were none, the minutes were accepted.

Committee members agreed that the PBMS approach to environmental measurements promises to offer better data, at lower cost, and in a more timely manner than can be achieved under EPA's current prescriptive system. They also agreed that there appear to be several key elements that must be successfully addressed in order that the PBMS approach be accepted by key stakeholders. While PBMS is a federal initiative, it is nevertheless optional for adoption by the States as they implement environmental laws and regulations. This committee will attempt to identify these key elements and explore solutions that will assist with the widespread acceptance of PBMS by all stakeholders.

KEY ELEMENTS

Mr. Parr then asked for initial comments on the draft list of key elements (Attachment C). Following discussion, "consistency," "simplicity," "clarity of intent," and "scientific soundness" were added to the list. "Enforceability" was changed to "documentation," and "oversight" was removed.

Additional discussion included the necessity that measurements (the process as well as the measurement method) developed under a PBMS approach can be deemed acceptable to EPA before their use in enforcement contexts, otherwise regulated entities will not risk contracting for them. The issue of how the National Environmental Laboratory Accreditation Conference (NELAC) should approach PBMS was briefly discussed, with agreement that this is a transition period in which NELAC committees will be changing the standards to respond to new needs.

Discussion was then directed to each of the elements, in turn.

Legal Defensibility
There was a consensus that legal defensibility will be a key issue to the development and use of new measurement methods under PBMS. Laboratories and regulated entities will only use measurement methods that are known to be acceptable to the ultimate customer, EPA. Mr. Parr asked that committee members forward additional information to him by August 6, 1998 so he can refine this discussion prior to the next meeting.

Present wording	**Legal Defensibility**: *In a compliance dispute, the burden of proof shall rest with a regulatory agency, if the regulated entity has followed the PBMS requirements.*

Flexibility
It was noted that a laboratory operates under contractual arrangements with regulated entities who are disposed to insist that "approved" EPA methods be used. Hence, even as EPA fully implements PBMS, regulated entities may be unwilling to accept a perceived risk of using "non-EPA" methods for lack of training in its acceptability. And even if a regulated entity is willing to permit a laboratory to use a "best method," the laboratory will be unwilling to risk use of a method that is not known to be acceptable. Hence, timeliness in formal approval by EPA, whether by method-specific document or by published performance criteria appears essential. Additional work on this element will be done by Ms. Zoe Grosser, Mr. Larry LaFleur, and Dr. Barton Simmons.

Present wording	**Flexibility**: *Laboratories shall have unlimited flexibility to modify methods, or use new methods, as long as the PBMS requirements are met.*

Innovation
Following brief discussion, the following revised wording for this element was agreed on:

Present wording	**Innovation**: *The scientific community shall have an effective system for optimal EPA approval of new technologies.*

Regulatory Development
It was noted that a recommendation in a previous ELAB PBMS workgroup submitted in a report in July 1997 to ELAB suggested that EPA regulations be based on demonstrated achievable measurement technology and sample having the same level of analytical challenge as the matrix for which the regulation is intended. It was also noted that California requires scientific review of the scientific context of any promulgated regulation. Dr. Simmons will locate the specific wording for this issue.

Proper application of the required peer review process may assist in this context. It was also noted that the supporting data should not only address method development, but its successful application in the context of its regulatory use. Ms. Lara Autry will work on this element.

Present wording	**Regulatory Development**: *Laboratory analyses performed by EPA or other regulatory agencies in support of new regulations must demonstrate that the regulatory achievements can be achieved.*

Documentation (Enforceability)
Following a brief discussion, the following revised wording for this element was agreed on:

Present wording	**Documentation**: *The documentation required under PBMS must be sufficient for independent validation (i.e., auditing)*

Cost Effectiveness
Concern was expressed that the cost of demonstrating compliance of a PBMS method to EPA criteria would be prohibitively high and preclude method adoption, particularly by very small operations such as those in Publicly Owned Treatment Works (POTWs). It was noted that data quality criteria, such as initial demonstration of capability in the matrix of interest, for the intended purpose, should be required uniformly for "approved" EPA methods as well as methods developed under PBMS. Mr. Parr agreed to revise this element.

Present wording	**Cost Effectiveness**: *Requirements for PBMS for method validation, QC activities, documentation, etc., must be no more stringent than those required for prescriptive methods.*

Regulatory Compliance
Following brief discussion, the following wording for this element was agreed on:

Present wording	**Regulatory Compliance**: *Any regulated entity meeting the PBMS requirement, and whose lab results demonstrate compliance, will be judged to be in compliance.*

Consistency
Discussion included the need to include consistency in definitions (such as measurement quality objectives, method validation criteria). Wording is to be developed.

Present wording	**Consistency**: to be developed.

Simplicity
It was noted that simplicity of implementation will be essential for PBMS concepts to be adopted. This is seen as particularly important as States evaluate PBMS for application to their programs.

Present wording	**Simplicity**: to be developed.

Clarity of Intent
While this element relates to enforceability, there is a need for all stakeholders to understand the intent of various PBMS components as they are interpreted and implemented.

Present wording	**Clarity of Intent**: to be developed.

Scientifically Sound
It was noted that PBMS implementation should focus on specifying scientifically fundamental performance criteria, not stipulating operational procedures or conditions.

Present wording	**Scientifically Sound**: to be developed.

NEXT MEETING

Arrangements have been requested for regular teleconfererence lines at two-week intervals. Mr. Parr will alert committee members when he is informed of the details.

Attachment A

ACTION ITEMS
ELAB PBMS WORKGROUP TELECONFERENCE
JULY 31, 1998

Action Items	Date to be Completed
All committee members should forward information to J. Parr on legal defensibility	8/6
Mr. Parr will revise legal defensibility wording	
Ms. Grosser, Mr. Lafleur, Dr. Simmons will revise flexibility wording	
Dr. Simmons will locate the specific wording in which California required scientific review of the scientific content of all regulations (re: regulatory development)	
Ms. Autry will reword regulatory development.	
Mr. Parr will work on rewording cost effectiveness	
Committee members will forward to **Mr. Parr** draft wording for the elements Regulatory Development, Cost Effectiveness, Consistency, Simplicity, Clarity of Intent, and Scientifically Sound.	

Attachment B

PARTICIPANTS
ELAB PBMS WORKGROUP TELECONFERENCE
JULY 31, 1998

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Attachment C

KEY ELEMENTS OF A PBMS PROGRAM

DRAFT 7/30/98

Legal Defensibility: In a compliance dispute, the burden of proof shall rest with a regulatory agency, if the regulated entity has followed the PBMS requirements.

Flexibility: Laboratories shall have unlimited flexibility to modify methods, or use new methods, as long as the PBMS requirements are met.

Innovation: Instrument manufacturers shall have an effective system for EPA approval of new technologies.

Regulatory Development: Laboratory analyses performed by EPA or other regulatory agencies in support of new regulations must demonstrate that the regulatory requirements can be achieved.

Enforceability: The documentation required under PBMS must be sufficient for accreditation.

Cost-Effectiveness: Requirements for PBMS for method validation, QC activities, documentation, etc., must be no more stringent than those required for prescriptive methods.

Regulatory Compliance: Any regulated entity meeting the PBMS requirement, and whose lab results demonstrate compliance, will be judged to be in compliance.

Oversight: An independent oversight process, including proficiency testing, laboratory inspections, and data audits must be implemented. NELAC is one approach which provides this oversight function.